**Louisiana Medicaid**
**Sodium Oxybate (Xyrem®) and**
**Calcium, Magnesium, Potassium and Sodium Oxybates (Xywav®)**

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for sodium oxybate (Xyrem®) and calcium, magnesium, potassium and sodium oxybates (Xywav®).

Additional Point-of-Sale edits may apply.

*These agents have **Black Box Warnings** and are subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

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## Calcium, Magnesium, Potassium and Sodium Oxybates (Xywav®)

### Approval Criteria

- **ONE** of the following is true:
  - The recipient is 7 years of age or older on date of request with a documented diagnosis of narcolepsy or cataplexy; **OR**
  - The recipient is 18 years of age or older on date of request with a documented diagnosis of idiopathic hypersomnia (IH); **AND**
- The prescribing provider is a Board-Certified Neurologist or a Board-Certified Sleep Medicine Physician; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the product prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

### Duration of initial authorization approval: 3 months

**Reauthorization Criteria**

- The recipient continues to meet all initial approval criteria; **AND**
- The prescriber **states on the request** that there is evidence of a positive response to therapy as indicated by a reduction in:
    - The frequency of cataplexy attacks; **OR**
    - Symptoms of excessive daytime sleepiness.

**Duration of reauthorization approval: 12 months**

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**Sodium Oxybate (Xyrem®)**

**Approval Criteria**

- The recipient is 7 years of age or older on date of request; **AND**
- The recipient has a documented diagnosis of narcolepsy or cataplexy; **AND**
- The prescribing provider is a Board-Certified Neurologist or a Board-Certified Sleep Medicine Physician; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the product prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

**Duration of initial authorization approval: 3 months**

**Reauthorization Criteria**

- The recipient continues to meet all initial approval criteria; **AND**
- The prescriber **states on the request** that there is evidence of a positive response to therapy as indicated by a reduction in:
    - The frequency of cataplexy attacks; **OR**
    - Symptoms of excessive daytime sleepiness.

**Duration of reauthorization approval: 12 months**

**References**

Xyrem (sodium oxybate) [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; September 2020. https://pp.jazzpharma.com/pi/xyrem.en.USPI.pdf

Xywav (calcium, magnesium, potassium and sodium oxybates) [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; August 2021. https://pp.jazzpharma.com/pi/xywav.en.USPI.pdf

| **Revision / Date** | **Implementation Date** |
|---|---|
| Xyrem policy created | January 2016 |
| Added Xywav™, modified clinical criteria to include age, formatting changes, updated references / October 2020 | April 2021 |
| Added new indication for Xywav®, formatting changes, updated references / August 2021 | January 2022 |
| Removed POS edits / December 2021 | January 2022 |